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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/830,300      | 07/05/2001  | Achim Berthold       | R00282US (#90568)   | 8251             |

28672 7590 10/19/2005  
D. PETER HOCHBERG CO. L.P.A.  
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CLEVELAND, OH 44114

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |  |  |  |
|------------------------------|--|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/830,300     | <b>Applicant(s)</b><br>BERTHOLD, ACHIM |  |
|                              | <b>Examiner</b><br>Sharmila S. Gollamudi | <b>Art Unit</b><br>1616                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1616

### DETAILED ACTION

Request of Amendments/Remarks filed on 7/1/05 is acknowledged. Claims **33-43** are pending in this application. Claims 8-14, 23, and 26-32 are withdrawn from consideration and claims 1-32 stand cancelled.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 33-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.**

The instant specification has support for three polymer-containing layers as evidenced by Figure 1 in the specification. However, the specification and Figure 1 only provides support for a system that has two layers with different glass transition temperatures and not three. This is evidenced by Figure 1 and page 10. Thus, it appears the recitation “the glass temperature Tg1 of the polymer of the first layer and the glass transition temperature of the Tg3 of the polymer of said third layer are identical *or different* does not have support since there is only support for the first layer and third layer having identical glass temperatures. Therefore, “different” is new matter. The examiner notes that in the office action dated 7/2/03 wherein the examiner suggested

Art Unit: 1616

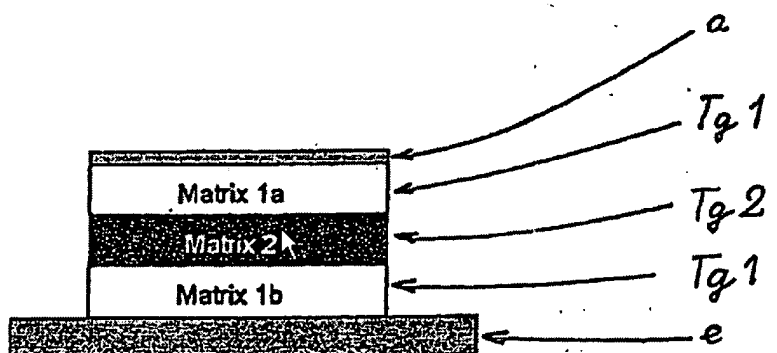
that the third layer be defined as Tg3, but this suggestion was based on the assumption there was support for the amended word “different”.

If applicant contends there is support, the applicant is requested to point to the exact page and line of the instant specification.

### *Response to Arguments*

Applicant argues that age 9, lines 1-2 and page 10, lines 1-5 provides support for different glass transition temperatures.

Applicant's arguments filed 7/1/05 have been fully considered but they are not persuasive. The examiner notes page 9 wherein the specification states that “the layers differ in their glass temperature” and acknowledges that applicant has support for two layers that have two different glass layers. However, the applicant does not have support for Tg3, let alone the third layer having a different glass transition temperature from the other two; this is clearly evidenced by the drawings. The drawing and page 10 clearly show a transdermal with three polymer layers but only two different glass transition temperature.



Art Unit: 1616

The examiner points out that in the Office Action of 7/2/03, the examiner indicated that the terminology Tg3 should be used if the third layer denoted a different glass temperature from the other two layers; however this was suggested assuming applicant could provided support in the specification.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 33-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al (5,151,271) by itself or in view of Patnode et al (6,063,838).**

Otsuka et al teaches a pressure sensitive adhering composite medicinal preparation to provide drug supply to the skin. The composite comprises **at least** two layers, namely **at least one** pressure-adhering macromolecular layer substance layer and polymer layer adjacent to the macromolecular substance layer. See abstract and column 2, lines 1-10.

Art Unit: 1616

The polymer layer contains a polymer or copolymer that has a glass transition temperature (T<sub>g</sub>) of not lower than -50 degrees Celsius, preferably -45 to +45. See column 2, lines 20-25. This allows an increased degree of diffusion therein of the drug and adjuvant but also does not deteriorate the physical strength of the device. The polymer layer may be made of methacrylate polymers. See column 2, lines 55-65.

The macromolecular layer functions to secure the preparation to the skin, be compatible with the drug and adjuvant, and allow release of the drug. This layer has pressure sensitive polymers with a T<sub>g</sub> of -70 to -10 degrees Celsius. This temperature allows increased shape holding property, does not cause skin irritation, and does not leave a residue when peeled off. See column 3, lines 1-25. The macromolecular layer is made of various monomers including methacrylic acid esters. Further, the macromolecular layer contains the drug and adjuvant.

The examples teach the use of two layers with different glass transition temperatures. For instance, example 1 teaches the macromolecular layer containing a drug with a T<sub>g</sub> of -55 degrees C and the polymer layer with a T<sub>g</sub> of -13 degrees C. The macromolecular layer is coated onto a release liner. The polymer layer is coated onto a polyester film. Note the polyester layer reads on the protective layer. Then the polymer film is pressed onto the macromolecular layer. Lastly, Otsuka teaches the use of various percutaneous drugs and the combination of two or more. See column 5, lines 15-51.

Although Otsuka suggests more than two polymer layers, the reference does not exemplify the third layer.

However, firstly it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Otsuka and incorporate a third polymer

Art Unit: 1616

containing layer. One would have been motivated to do so since Otsuka teaches that the composite should contain *at least* two layers and in particular *at least one* macromolecular layer; thus suggesting the incorporation of more than one macromolecular layer. Therefore, if a skilled artisan followed the suggestion provided by Otsuka and utilized two macromolecular layers, a skilled artisan would arrive at the instant invention wherein the invention would have a macromolecular layer corresponding to Tg1, a polymer layer corresponding to Tg2, and the second macromolecular layer corresponding to Tg3. Additionally, it should be noted that polymer layer (Tg2) has a higher temperature than the macromolecular layer as taught by Otsuka. Furthermore, the polymer layer would be sandwiched in between the two macromolecular layers instantly claimed since Otsuka teaches the macromolecular layer must be in contact and adjacent to the polymer layer (see column 2, lines 5-10). Therefore, if a skilled artisan utilized two macromolecular layers, the instant sandwich type configuration, wherein the polymer layer is in the middle, would be required to satisfy Otsuka's criteria that the macromolecular layer must be in contact with the polymer layer. Thus, the sandwich type configuration would enable both macromolecular layers to be in contact and adjacent to the polymer layer. Further, the claims recite that the temperature of the third layer (Tg3) may be the same or different than Tg1, an additional macromolecular layer with an identical Tg of the first macromolecular layer would still read on the claims.

Patnode et al teach a blended pressure-sensitive adhesive which is formed from at least two polymeric materials with at least one is a pressure sensitive adhesive. Patnode teaches the transdermal art provides for several types of matrices and all devices basically contain a drug formulation, an adhesive to maintain contact with the patient's skin, a release liner to protect the

Art Unit: 1616

device in storage, and a backing. See column 12, lines 60-66. Patnode teaches a embodiment wherein a multilaminate device contains a backing, an adhesive layer which contains the drug and excipients, a membrane that controls the rate at which the drug is diffused to the skin, a second adhesive layer, and a release layer. See column 13, lines 20-30 and Figure 15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Otsuka et al and Patnode and utilize a third pressure sensitive layer. Patnode teaches a multilaminate device containing a backing, a pressure sensitive adhesive layer which contains the drug and excipients, a membrane that controls the rate at which the drug is diffused to the skin, a second pressure sensitive adhesive layer, and a release layer. Therefore one would have been motivated to look to Patnode et al who teach a multilaminate transdermal device to construct Otsuka's suggested device of at least two macromolecular pressure sensitive layers.

### ***Response to Arguments***

Applicant argues that Otsuka does not disclose an arrangement as set forth in the instant claims. Applicant argues that Otsuka does not teach sandwiching the polymer-containing layer having a high Tg (Tg2) in between Tg1 and Tg3. Applicant argues that Patnode does not make up for the deficiencies of Otsuka.

Applicant's arguments filed 7/1/05 have been fully considered but they are not persuasive. As discussed in the above rejection, the examiner points out that by following Otsuka's suggestion and criteria that the macromolecular layer must be in contact with the polymer layer, a skilled artisan would arrive at the instant invention. Firstly, Otsuka teaches "at least one macro-molecular substance layer" which is a clear suggestion that more than one



Art Unit: 1616

macromolecular layer may be used. However, Otsuka teaches the macromolecular layer and polymer layer must be in contact to each other which is a critical feature for the device to work. See column 2, lines 1-10. Therefore, if a skilled artisan utilized two macromolecular layers as suggested by Otsuka, the only configuration that would work is sandwiching the polymer layer between the two macromolecular layers which enables both macromolecular layers to be in contact and adjacent to the polymer layer.

Patnode teaches a multi-laminate device comprising a backing, a pressure sensitive adhesive layer containing a drug, a membrane layer that controls the rate at which the drug is diffused to the skin (sandwiched between the two adhesive layers), a second pressure sensitive adhesive layer, and a release layer. Therefore, a skilled artisan would look to Patnode to make Otsuka's suggested device since Patnode's two pressure sensitive adhesive layer correspond to Otsuka's pressure sensitive macromolecular layer and Patnode's membrane layer corresponds to Otsuka's polymer layer.

**Claims 33-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al (5,151,271) by itself or in view of Chien et al (5023084).**

Otsuka et al teaches a pressure sensitive adhering composite medicinal preparation to provide drug supply to the skin. The composite comprises **at least** two layers, namely **at least one** pressure-adhering macromolecular layer substance layer and polymer layer adjacent to the macromolecular substance layer. See abstract and column 2, lines 1-10.

The polymer layer contains a polymer or copolymer that has a glass transition temperature (T<sub>g</sub>) of not lower than -50 degrees Celsius, preferably -45 to +45. See column 2, lines 20-25. This allows an increased degree of diffusion therein of the drug and adjuvant but

Art Unit: 1616

also does not deteriorate the physical strength of the device. The polymer layer may be made of methacrylate polymers. See column 2, lines 55-65.

The macromolecular layer functions to secure the preparation to the skin, be compatible with the drug and adjuvant, and allow release of the drug. This layer has pressure sensitive polymers with a Tg of  $-70$  to  $-10$  degrees Celsius. This temperature allows increased shape holding property, does not cause skin irritation, and does not leave a residue when peeled off. See column 3, lines 1-25. The macromolecular layer is made of various monomers including methacrylic acid esters. Further, the macromolecular layer contains the drug and adjuvant.

The examples teach the use of two layers with different glass transition temperatures. For instance, example 1 teaches the macromolecular layer containing a drug with a Tg of  $-55$  degrees C and the polymer layer with a Tg of  $-13$  degrees C. The macromolecular layer is coated onto a release liner. The polymer layer is coated onto a polyester film. Note the polyester layer reads on the protective layer. Then the polymer film is pressed onto the macromolecular layer. Lastly, Otsuka teaches the use of various percutaneous drugs and the combination of two or more. See column 5, lines 15-51.

Although Otsuka suggests more than two polymer layers, the reference does not exemplify the third layer.

However, firstly it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Otsuka and incorporate a third polymer containing layer. One would have been motivated to do so since Otsuka teaches that the composite should contain *at least* two layers and in particular *at least one* macromolecular layer; thus suggesting the incorporation of more than one macromolecular layer. Therefore, if a skilled

Art Unit: 1616

artisan followed the suggestion provided by Otsuka and utilized two macromolecular layers, a skilled artisan would arrive at the instant invention wherein the invention would have a macromolecular layer corresponding to Tg1, a polymer layer corresponding to Tg2, and the second macromolecular layer corresponding to Tg3. Additionally, it should be noted that polymer layer (Tg2) has a higher temperature than the macromolecular layer as taught by Otsuka. Furthermore, the polymer layer would be sandwiched in between the two macromolecular layers instantly claimed since Otsuka teaches the macromolecular layer must be in contact and adjacent to the polymer layer (see column 2, lines 5-10). Therefore, if a skilled artisan utilized two macromolecular layers, the instant sandwich type configuration, wherein the polymer layer is in the middle, would be required to satisfy Otsuka's criteria that the macromolecular layer must be in contact with the polymer layer. Thus, the sandwich type configuration would enable both macromolecular layers to be in contact and adjacent to the polymer layer. Further, the claims recite that the temperature of the third layer (Tg3) may be the same or different than Tg1, an additional macromolecular layer with an identical Tg of the first macromolecular layer would still read on the claims.

Chien et al disclose a transdermal system that provides a combination of drugs (estrogen and progestin) in a unit dosage. Example 8 teaches the transdermal contains a first adhesive layer that contains the estrogen and a pressure sensitive adhesive, a separating layer containing polyisobutylene polymer, and a third adhesive layer that contains the progesten and a pressure sensitive adhesive.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Otsuka et al and Chien et al and incorporate a third

Art Unit: 1616

macromolecular pressure sensitive drug containing layer. One would have been motivated to do so since Otsuka teaches that the composite should contain *at least* two layers and teaches at least one macromolecular layer (which is an implicit teaching of more than one macromolecular layer); therefore suggesting the incorporation of more than one pressure sensitive macromolecular layer. Further, Chien teaches a multilaminate device containing a first adhesive layer with a first drug which correlates to Otsuka's macromolecular layer, a separating layer which correlates to Otsuka's polymer layer, and another adhesive layer containing a second drug, which correlates to Otsuka's suggested second macromolecular layer. Therefore, if one desired to utilize different drugs for combination therapy as known in the prior art, one would have been motivated to utilize another pressure sensitive adhesive macromolecular layer, which has a lower glass temperature than the polymer layer.

### ***Response to Arguments***

Applicant argues that Otsuka does not disclose an arrangement as set forth in the instant claims. Applicant argues that Otsuka does not teach sandwiching the polymer-containing layer having a high Tg (Tg2) in between Tg1 and Tg3. Applicant argues that Chien teaches a Tg2 temperature that is lower than Tg1 and Tg2 and thus one would not have been motivated to look to Chien.

Applicant's arguments filed 7/1/05 have been fully considered but they are not persuasive. As discussed in the above rejection, the examiner points out that by following Otsuka's suggestion and criteria that the macromolecular layer must be in contact with the polymer layer, a skilled artisan would arrive at the instant invention. Firstly, Otsuka teaches "at least one macro-molecular substance layer" which is a clear suggestion that more than one

Art Unit: 1616

macromolecular layer may be used. However, Otsuka teaches the macromolecular layer and polymer layer must be in contact to each other which is a critical feature for the device to work. See column 2, lines 1-10. Therefore, if a skilled artisan utilized two macromolecular layers as suggested by Otsuka, the only configuration that would work is sandwiching the polymer layer between the two macromolecular layers which enables both macromolecular layers to be in contact and adjacent to the polymer layer.

With regard to Chien, the examiner relies on Chien to further provide the motivation to utilize two macromolecular layers as suggested by Otsuka and not the glass temperatures of each layer since Otsuka is not deficient in this sense. Chien provides the motivation to follow Otsuka's suggestion of using more than one pressure sensitive adhesive macromolecular layer. Therefore, if a skilled artisan desired to provide combination therapy wherein one device contained two different drugs, one would have been motivated to use two pressure sensitive macromolecular layers wherein each respective layer would comprise a different drug.

### ***Conclusion***

None of the claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1616

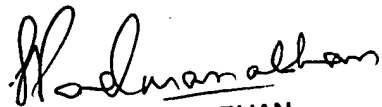
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi  
Examiner  
Art Unit 1616

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER